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GENENTECH, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GENENTECH, INC.

Plaintiff,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA, a Pennsylvania non-profit corporation.

Defendant.

Case No. C 10-2037 LHK

PLAINTIFF'S REPLY MEMORANDUM IN SUPPORT OF MOTION TO FILE FIRST AMENDED COMPLAINT AND FIRST AMENDED ANSWER

Date: May 12, 2011
Time: 1:30 p.m.
Dept: Courtroom 4, Fifth Floor
Judge: Hon. Lucy H. Koh

Date Comp. Filed: May 11, 2010
Trial Date: None Set

[REDACTED – PUBLIC VERSION]

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I. INTRODUCTION

Penn does not (and can not) seriously dispute that Genentech has met the requisite criteria governing motions to amend. After all, the Court must apply Federal Rule of Civil Procedure 15 "with extreme liberality," drawing all inferences in favor of permitting amendment. *Owens v. Kaiser Foundation Health Plan, Inc.*, 244 F.3d 708, 712 (9th Cir. 2001). Indeed, as the party opposing the motion for leave to amend, ***Penn*** bears the burden of showing why leave to amend should not be granted. *Senza-Gel Corp. v. Seiffhart*, 803 F.2d 661, 666 (9th Cir. 1986). Here, Penn has failed to identify any meaningful shortcoming in Genentech's inequitable-conduct allegations, which amply identify "the specific who, what, when, where, and how" of the material misrepresentations Penn perpetrated, and include detailed allegations of knowledge and intent based on the underlying facts. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009).

Instead of seriously challenging Genentech's motion, Penn instead focuses its opposition on testing out its potential rebuttal to the asserted inequitable-conduct defenses, namely (a) that even though Drs. Greene and Katsumata tried and failed to demonstrate "an antibody which specifically binds to p185 ***in sufficient amount*** to down regulate the overexpressed p185" at the dosage reported in the patent, their subjective belief that the experiment ***should have*** worked excuses their misrepresentation to the PTO that the experiment ***in fact*** worked; (b) that Drs. Greene and Katsumata did not know the patent application they each affirmed under oath contained several material misrepresentations about the results of their experiments; and (c) that the 1993 datasheets Penn produced and relied on to establish the dates for conception and reduction to practice, and which report ***practically identical*** experimental results to those disclosed in the '752 patent ***except for*** the inventors' central conclusion that "6 of 12 mice in [the high-dose treatment] group (50%) remained free of tumors at more than 90 weeks of age," may not be related to the '752 patent at all. Opp. at 15-17; 20-22; 24. These lawyerly arguments, in addition to being irrelevant to evaluating Genentech's motion, lack factual basis. Genentech respectfully requests the Court grant its motion.

II. ARGUMENT

Penn's opposition consumes pages attempting to complicate straightforward applicable legal standards. Federal Rule of Civil Procedure 9(b) requires a plaintiff to identify "the circumstances constituting fraud so that the defendant can prepare an adequate answer from the allegations." *Odom v. Microsoft Corp.*, 486 F.3d 541, 553 (9th Cir. 2007) (en banc). Rule 9(b) in no way negates, however, the requirements of Rule 8, which mandates short, simple and concise allegations as are reasonable under the circumstances. *Carrigan v. Cal. State Legislature*, 263 F.2d 560 (9th Cir. 1959). Nor does the heightened pleading requirement of Rule 9(b) require, as Penn suggests, that Genentech definitively prove the merits of its claim in its pleading or on this motion.[1] "What is determinative here is [whether Penn] was given fair notice of the basis for [Genentech]'s inequitable conduct defense." *Aerocrine AB v. Apieron Inc.*, 2010 WL 1225090 at *10 (D. Del. 2010). That notice is deemed provided if the amended pleadings satisfy the pleading requirements under Rule 9(b). Genentech's allegations meet this standard.

A. Genentech has alleged sufficient facts to support its allegation that Katsumata and Greene falsified data in the '752 patent specification.

1. Genentech's allegations provide the "who, what, when, where, and how" required to satisfy Federal Rule of Civil Procedure 9(b).

Genentech alleges inventors Katsumata and Greene knowingly misrepresented to the PTO that "6 of 12 mice in [the high-dose treatment] group (50%) remained free of tumors at more than 90 weeks of age," and that this data "demonstrate[] for the first time that immunological manipulations of p185neuT can effectively prevent the development of genetically induced breast tumors in a rodent model." FAC ¶¶ 40-41. Genentech's First Amended Complaint and Answer identify the who, what, when, where and how of this material misrepresentation. *Exergen*, 575 F.3d at 1327. The ***"who"*** are two '752 patent inventors: Drs.

[1] Penn claims Genentech's inequitable conduct allegations are "subject to strict judicial scrutiny." Opp. at 9. This is not the applicable legal standard on a motion to amend. Penn's citation to *Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988), which involves appellate review of a trial court's summary judgment order and does not even mention Federal Rule of Civil Procedure 9(b), provides no authority whatsoever for Penn's assertion.

Greene and Katsumata. FAC ¶ 40-42. The ***"what"*** is the inventors' misrepresentations that "6 of 12 mice in [the high-dose treatment] group (50%) remained free of tumors at more than 90 weeks of age" and that "all animals that developed malignancy in the high-dosage group had only a single tumor." FAC ¶¶ 40-45, 53-56. The ***"when"*** and ***"where"*** as to the misrepresentations are: the '752 patent application, the June 30, 2000 Response and Amendment to the '752 patent application, and the October 10, 2002 Amendment to the '752 patent application. FAC ¶ 39-40, 53-55. The ***"how"*** is that a reasonable examiner would have relied on the falsified data from the high-dose experiment to determine the patentability of claim 1 because it "offers the *only* data in the patent application to support a claim to a method that 'inhibits development into breast cancer cells of breast cells that overexpress p185.'" FAC ¶¶ 49-52. Genentech has also cited facts showing that the inventors repeatedly cited the false data to overcome PTO rejections. *See* FAC ¶ 52-54.[2] Thus, Genentech has alleged numerous facts establishing materiality.

Genentech has also pled facts from which the Court may reasonably infer that Katsumata and/or Greene (1) knew the experimental data did not support the 50% allegation and (2) made these misrepresentations with the specific intent to deceive the PTO. *Exergen Corp.*, 575 F.3d at 1328-29. As to ***knowledge***, Genentech has alleged that [redacted] FAC ¶ 47. As to ***intent***, Genentech has alleged that "Katsumata and Greene's misrepresentation cannot be dismissed as a typographic error or accident, because they misdescribed both the number of mice and the duration that those mice lived tumor-free." FAC ¶ 46; *See Itex, Inc. v. Westex, Inc.*, 2010 WL 2901793 at *5 (N.D. Ill. July, 21, 2010) ("[A]t the pleading stage, deceptive intent need only be a *reasonable* inference, not necessarily the *single most reasonable* inference.")

[2] *See* FAC ¶ 53 (stating that the '752 patent applicants argued in response to an obviousness rejection that the data showing "mice treated with the antibody of the invention did not develop tumors even after ninety weeks of age" renders "the applicants' invention particularly useful as a post operative treatment"); *id.* ¶ 54 (the applicants argued in response to a rejection under 35 U.S.C. § 112, paragraph 1, that "50% [of the treated mice] remain tumor free at more than 90 weeks of age (page 13, lines 12-15) [and] [h]ence, the inhibition of tumor formation necessarily inhibits tumorigenesis of a cell that overexpresses p185 into a fully developed tumor.")

2. Penn's extraneous merits arguments are irrelevant and unpersuasive.

Failing to challenge the sufficiency of Genentech's amended pleadings, Penn instead argues the underlying merits. Those arguments are irrelevant to Genentech's motion to amend. Even if they were relevant, they are unpersuasive. *First*, Penn argues that Greene and Katsumata wouldn't have known about the discrepancy between the real high-dose data and the inaccurate figure they reported to the PTO. Penn claims that when Dr. Katsumata testified [redacted] which testimony speaks for itself, he was actually just saying Greene was the "head of the laboratory where the project was carried out." *See* Opp. at 21. But a review of the cited testimony reveals just the contrary: [redacted] *See* Faulkner Decl. Ex. C at 43:8-10.

Likewise, Penn alleges that because Greene "oversaw numerous simultaneous projects," "managed a large number of researchers" and "spent significant time traveling," he couldn't possibly have known whether the underlying data actually supported the inventors' claim that 50% of the high-dose mice lived more than 90 weeks tumor-free. *Id.* Penn's own documents put the lie to this conjecture. On March 30, 1993, Greene gave a presentation entitled "Breast Cancer Therapy and Prevention: New Approaches." *See* Supplemental ("Suppl.") Faulkner Decl. Ex. 1 at 6. The following day, a press release covering Greene's talk described the age at which the mice "ordinarily … get cancer" – "35 weeks" – as well the age of the mice – "6 weeks" – when treatment began.[3] *See* Suppl. Faulkner Decl. Ex. 2 at UP0006141. Thus, Greene was keeping track, in detail, of the most recent data produced in his lab.

Penn likewise claims that although Katsumata testified [redacted]

[3] The press release stated: "Greene has experimented largely in mice that have been genetically manipulated to develop a form of cancer indistinguishable from neu-related breast cancer in people. Ordinarily, these animals get cancer at about 35 weeks of age. When the researchers began treating them with anti-neu antibodies at about 6 weeks of age, the appearance of cancer was delayed and half of the mice did not development [sic] malignancies at all. 'This was a thrilling experiment for us and holds tremendous promise for the treatment of malignancy,'

[redacted] Opp. at 21-22. It is astonishing that Drs. Greene and Katsumata would sign their names under penalty of perjury to a patent application predicated on *a single experiment* and then claim that they could not have been bothered to review the experiment's results. In any case, Genentech has properly and sufficiently alleged that, as the leader and supervisor of the project, Greene and Katsumata were aware of the data produced in the experiment. FAC ¶ 47.

Second, Penn claims that Drs. Greene and Katsumata's having misrepresented fundamental experimental data is not material because Genentech did not show "the PTO would even have cared that none of the [six] mice lived to 90 weeks." Opp. at 20. Suspending common sense as Penn's argument requires, Genentech has specifically alleged that [redacted] FAC ¶¶ 44-45 (emphasis added). Moreover, as noted above, the inventors repeated their misrepresentation of the high-dose experimental data – that "6 of 12 mice in [the high-dose treatment] group (50%) remained free of tumors at more than 90 weeks of age" – three times to overcome PTO rejections. *See* FAC ¶¶ 52-54. Accordingly, Genentech alleged that a reasonable patent examiner "would have found the true data that Katsumata and Greene concealed material to determine patentability of the '752 patent." *Id.* ¶ 51.[4]

Penn also argues against materiality on the basis that Genentech has not "establish[ed]" that the 1993 datasheets Penn produced during discovery "relate to the experiments disclosed in Example 2 of the '752 patent" Opp. at 24.[5] But ***Penn relied on these records as evidence of the***

Greene said." *See* Suppl. Faulkner Decl. Ex. 2 at UP0006141.

[4] Penn also injects a false factual dispute claiming that Genentech "independently corroborated the inventors' discovery" when it tested a completely different antibody, under a different experimental protocol and got substantially different experimental results than the inventors did in their claimed studies. This claim, which Genentech certainly disputes, in no way even bears on the *materiality* of the inventors' misrepresentations regarding the high-dose experimental data.

[5] Notably, Penn also claims Genentech "fails to allege" that the datasheets Genentech discovered were "used … in preparing the '752 patent application," but in the next breath complains that

inventors' conception and reduction to practice of the claimed invention. *See* Faulkner Decl. Ex. D; FAC ¶ 44 (citing University of Pennsylvania's Supplemental Response to Interrogatory No. 1). And, when asked to provide Genentech with the original documents supporting the 1995 Katsumata paper and corresponding to the '752 patent experiments,[6] Penn produced a redwell containing the very same 1993 datasheets. Williams Decl. ¶¶ 2, 4-6. Penn cannot selectively choose to rely on the datasheets when they support its case, but then ask the Court to look the other way when the very same documents evidence a fraud on the PTO. Moreover, the 1993 datasheets were contained within a redwell folder labeled [redacted] *See* Williams Decl. ¶ 5. Accordingly, based upon Penn's own admission and the striking similarities between the data in the patent and the data from the 1993 datasheets (demonstrated below), the Court may reasonably infer that the experiments disclosed in Example 2 of the patent and memorialized in the 1993 datasheets are one and the same.

Finally, as to intent, Penn predictably spins the inconsistencies between the inventors' claims and the 1993 datasheets as mere "irregularity" or "error." *See* Opp. at 20-22. Anticipating this response, Genentech specifically alleged that "Katsumata and Greene's misrepresentation cannot be dismissed as a typographic error or accident, because they misdescribed both the number of mice and the duration that those mice lived tumor-free." FAC ¶ 46. Indeed, a comparison of the experimental data reported in the '752 patent and the underlying data in the 1993 datasheets demonstrates that Drs. Greene and Katsumata reported ***all*** of the experimental results with painstaking accuracy ***except for the most important one of all***:

Genentech's "allegation that the datasheets … relate to the experiments disclosed in Example 2 of the patent is simply conclusory." Opp. at 24. Penn can't have it both ways. In any event, Genentech did so allege. *See, e.g.,* FAC ¶¶ 39 and 42.

[6] Dr. Katsumata admitted during his deposition that [redacted] *See* Faulkner Decl. Ex. C at 66:21-67:4.

	Patent (col. 7-8)	1993 Datasheets	Bates No.[7]
Number of mice in high dose group	12	[redacted]	UP0009051
Number of mice in low dose group	11	[redacted]	UP0009089-90
Number of mice in control group 1 (PBS1)	12	[redacted]	UP0009071
Number of mice in control group 2 (PBS2)	10	[redacted]	UP0009051
Age of mouse in control groups that had earliest tumor	28 weeks	[redacted]	UP0009071, UP0009105
Age of mouse in high dose group that had earliest tumor	45.6 weeks	[redacted]	UP0009051
Age of mouse in low dose group that had earliest tumor	31 weeks	[redacted]	UP0009105
Age of oldest mouse in control groups to get tumor	72 weeks	[redacted]	UP0009071, UP0009105
Age of oldest mouse in low dose group to get tumor	75 weeks	[redacted]	UP0009105
Average age of tumor appearance in low dose group	50.7 (+/- 2.7) weeks	[redacted]	UP0009105
Average age of tumor appearance in control group 1	42.8 (+/- 3.2) weeks	[redacted]	UP0009105
Average age of tumor appearance in control group 2	45 (+/- 3) weeks	[redacted]	UP0009051, UP0009105
Percentage of mice that lived 90 weeks or more tumor free	**50%**	[redacted]	**UP0009051**

The fact that Drs. Greene and Katsumata accurately reported their experimental results ***but for*** the one result on which their alleged invention turns, and cited that mispresentation ***repeatedly*** to overcome PTO rejections, supports a reasonable inference that the misrepresentation was deliberate and intentional. Thus, Genentech has alleged sufficient facts from which the Court could ***conclude***, let alone *reasonably* infer, that Katsumata and Greene perpetrated a fraud on the PTO. *Cf. Itex*, 2010 WL 2901793 at *5 (granting leave to add

[7] *See* Williams Decl. Ex. C.

allegation of inequitable conduct where inventor did not report, but retested unfavorable results, but chose not to retest favorable results and rejecting plaintiff's argument that use of averages in reporting results was routine, and that there were "many plausible reasons for 'retests' and 'averaging' of scientific data"). Genentech need plead nothing further.

B. Genentech has sufficiently alleged that Katsumata and Greene knowingly misrepresented to the PTO that the '752 patent specification supports claim 1's downregulation amendment.

1. Genentech's detailed factual allegations more than satisfy the basic requirements of Rule 9(b).

Genentech has alleged that Drs. Greene and Katsumata "[mis]represented to the PTO that the examiner could find support for the 2003 down-regulation amendment to claim 1 'throughout the specification, e.g., in Examples 1 and 2 and in the text set forth [in the patent].'" FAC ¶ 93. That downregulation amendment claimed "an antibody which specifically binds to p185 ***in sufficient amount*** to down regulate the overexpressed p185." *See* FAC ¶ 62; Faulkner Decl. Ex. I at 2 (emphasis added). The inventors' misrepresentation is material to whether the '752 patent's specification supports claim 1's downregulation element "***in sufficient amount***."

Genentech's allegation is supported by specific facts in the First Amended Complaint and Answer indicating the who, what, when, where and how of this material misrepresentation. *Exergen*, 575 F.3d at 1327. The ***"who"*** are the '752 patent's inventors: Drs. Greene and Katsumata. FAC ¶ 63. The ***"what"*** is the inventors' above-cited misrepresentation. *Id.* The ***"when"*** and ***"where"*** – describing when and where the inventors made the misrepresentation – is in the July 1, 2003 Amendment to the '752 patent application. *Id.*; Faulkner Decl. Ex. I at 5. The ***"how"*** – describing how a reasonable examiner would have relied on the misrepresentation in determining patentability – is that a reasonable examiner would have relied on the misrepresentation "in determining whether ***one of ordinary skill in the art*** would conclude that there was adequate written description in the specification for the down-regulation amendment to claim 1, whether the specification enabled the down-regulation amendment to claim 1, and/or whether the inventors had reduced the claimed invention to practice when they filed their application." *Id.* ¶ 96 (emphasis added).

Genentech has also pled numerous facts from which the Court may reasonably infer that Katsumata and/or Greene (1) knew their statement—that the examiner could find support "throughout the specification" for the down-regulation amendment claiming "an antibody which specifically binds to p185 ***in sufficient amount*** to down regulate the overexpressed p185"—was false and (2) made this misrepresentation with the specific intent to deceive the PTO. *Exergen Corp.*, 575 F.3d at 1328-29. As to ***knowledge***, Genentech has alleged facts showing that *numerous scientists*, i.e., numerous persons of skill in the art, told Katsumata and Greene *repeatedly* that the very same data found in the '752 patent and cited in support of the downregulation amendment to claim 1 *did not* support the same downregulation claim in a draft manuscript the inventors sought to publish six months before filing the '752 patent application. *See* FAC ¶¶ 67-77. The inventors addressed their critics by designing and executing new experiments that ultimately used ***a much higher antibody dose*** not disclosed in the patent; yet, as discussed below, these experiments were never disclosed to the PTO. *Id.* Genentech also cited to Katsumata's admission during his deposition [redacted]

As to ***knowledge*** and ***intent***, Genentech has alleged that although Katsumata and Greene knew that the excluded experiments were necessary to support the amendment claiming "an antibody which specifically binds to p185 in sufficient amount to down regulate the overexpressed p185," they purposefully withheld that data because it contradicted the argument that the dose disclosed in the patent provided Section 112 support for the amendment. Specifically, Genentech cited to Katsumata's admissions that in executing the undisclosed experiments, [redacted] FAC ¶¶ 83-84. Moreover, Genentech has alleged that the inventors knew the discrepancy between the disclosed and undisclosed data sets was material

because numerous peer scientists cautioned that, taken together, the data appeared "flawed" and seemed to indicate a "requirement" of a higher antibody dose to achieve downregulation than the dose disclosed in the first data set – i.e., the only data disclosed in the '752 patent. *Id.* ¶¶ 86-89.

Taken together, these facts more than "comprise a plausible factual scenario from which the Court can reasonably infer knowledge and deceptive intent on the part of the ['752] patent's inventors." *Aerocrine*, 2010 WL 1225090 at *10 (citing *Exergen*, 575 F.3d at 1327 n. 5 ("A reasonable inference is one that is plausible and that flows logically from the facts alleged.")) This is sufficient under *Exergen.*

2. Penn's extraneous merits arguments are irrelevant and unpersuasive.

Penn does not dispute that Genentech has adequately pled the specific who, what, when, where and how of this material misrepresentation. Rather, Penn disputes whether the facts inexorably prove the inventors intended to mislead the PTO. For example, Penn argues variously and at length that the inventors may have persisted in believing their initial data was sufficient to support the downregulation claim despite numerous rejections and warnings to the contrary issued by their peer scientists. *See* Opp. at 15-16.[8] Penn further argues Genentech "provides no basis for imputing to the inventors" the reviewers' warnings, and that instead Genentech must prove the inventors adopted their peers' beliefs. *Id.*

This assertion is wrong on the facts and the law. Genentech has alleged that in response to their peers' warnings, the inventors "did not protest," but rather "implicitly agreed by conducting a new set of experiments designed to show down-regulation." FAC ¶ 68. Indeed, Penn acknowledges Genentech's supporting allegation, but then claims in the next breath (citing no support) that "it is routine practice" for authors to provide additional experiments without comment. Opp'n Br. at 16. Neither Rule 9(b) nor *Exergen* require Genentech to prove, at the

[8] Curiously, Penn argues that the inventors persisted in believing their purported invention "involved" downregulation. *See, e.g.*, Opp. at 18 ("Genentech's pleading contains no allegation of facts that would support a reasonable inference that the inventors subjectively believed their invention did not involve downregulation.") Penn misapprehends the complaint. Genentech's allegations are directed to the inventors' representation to the PTO that ***the specific data and statements in the '752 patent specification*** supported their downregulation amendment to the '752 patent claims – ***not*** whether the inventors may have believed their "invention" somehow "involved" downregulation. Thus, much of Penn's argument misses the point.

pleading stage and with minimal discovery, the merits of its claim. *The Braun Corp. v. Vantage Mobility Int'l, LLC*, 2010 WL 403749 at *5 (N.D. Ind. Jan. 27, 2010) ("The heightened pleading requirements of Rule 9(b) do not require that [the defendant] definitively prove the merits of its claim.")

Penn also claims, without citing any authority, that Genentech must prove inventors Katsumata and Greene were *personally* involved in the ministerial task of preparing the July 1, 2003 Amendment to the '752 patent application containing the misrepresentation. Opp. at 18. But this is wrong for several reasons. *First*, the misrepresentation at issue here concerns the very basic and central premise of whether the '752 patent's specification supports claim 1's downregulation element "in sufficient amount." In arguing that "[t]he downregulation limitation" was added "years later" and that Greene and Katsumata were not "involved in adding the limitation," *see* Opp. at 18, Penn appears to claim that neither Greene nor Katsumata was ever aware that the patent contained the downregulation claim. This suggestion defies common sense as well as the facts. Dr. Greene participated in a telephonic interview with the examiner to discuss the '752 patent shortly before the submission of the Amendment.[9] *See* Faulkner Decl. Ex. H at 3. He thus would have reviewed and perhaps discussed with the Examiner the pending claim amendments—which included a downregulation requirement.

Second, under 37 C.F.R. § 1.56(c), each inventor named in the application owes a duty of disclosure and candor to the PTO. This duty does not end when the application is filed, but "extends throughout the patent's entire prosecution history." *Fox Industries, Inc. v. Structural Preservation Systems, Inc.*, 922 F.2d 801, 803-04 (Fed. Cir. 1990). The inventors cannot shirk this duty by burying their head in the sand, and refusing to pass on material information to their agents. *Taltech Ltd. v. Esquel Enterprises Ltd.*, 604 F.3d 1324, 1334 (Fed. Cir. 2010) (*citing FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 n. 8 (Fed. Cir. 1987) ("[T]he

[9] Moreover, the August 2001 Amendment to the '752 patent states that "[d]uring the Examiner's interview" Dr. Greene explained that "the methods of the present invention are directed at downregulating the activity of p185." *See* Faulkner Decl. Ex. H at 3; see also "Dr. Greene additionally explained that … [t]he data in the specification show that by down-regulating p185 activity … the mice do not develop tumor cells…." *Id.* at 4. Thus, Greene was demonstrably involved in the '752 patent's prosecution and knew it contained a downregulation limitation.

knowledge and actions of applicant's attorney are chargeable to applicant.")). At the time that the '752 patent application was filed, the inventors already knew that the initial data had been questioned and were in the process of supervising new experiments to try and determine what amount of antibody was sufficient to cause downregulation. When they learned that the amount in the patent was not sufficient, there was a duty to apprise the examiner.

C. Genentech's allegation that patent agent Bernstein misrepresented key facts to secure grant of the '752 patent also meets the pleading standard under Rule 9(b).

Genentech has alleged Penn representative Mitchell Bernstein misrepresented to the PTO on numerous occasions that Penn had been granted an extension of time to file a brief appealing the '752 patent's abandonment, and that Bernstein did so in order to deceive the PTO into reviving the abandoned '752 patent.[10] Penn does not dispute that Genentech has sufficiently alleged the who, what, when, and where of this material misrepresentation. *Exergen*, 575 F.3d at 1327. Nor could it. As established below, Genentech has properly alleged each of these facts.

The ***"who"*** is Mitchell Bernstein. *See, e.g.,* FAC ¶ 125. The ***"what"*** is Bernstein's multiple misrepresentations to the PTO that it had actually granted Penn a one month extension of time to file its appeal brief. FAC ¶¶ 125-126 and 133.[11] The ***"when"*** and ***"where"*** as to the misrepresentations are: the February 20, 2004 and May 10, 2004 Petitions for Revival. FAC ¶¶ 125-126 and 133. The ***"how"*** is that the PTO relied on Bernstein's misrepresentations in finding that the application became abandoned on April 18, 2002 rather than April 10, 2002, and that this

[10] Genentech does not, and did not intend to, allege fraud by Mark DeLuca as a basis for its inequitable conduct defense. Genentech will strike DeLuca's name from paragraph 37 of the proposed First Amended Complaint and paragraph 24 of the First Amended Answer.

[11] *See* FAC ¶ 126 ("The subject application became abandoned for failure to timely file an appeal brief due April 17, 2003, including *extensions of time actually granted*" (Faulkner Decl. Ex. P at UP0073227); "the application became abandoned for failure to timely file an Appeal Brief *due on April 17, 2002, …*" (*id.*); "The application therefore became abandoned on April 18, 2002, the day after Applicant failed to file an Appeal Brief within the required period, including *the granted one month extension of time*." (Faulkner Decl. Ex. P at UP0073228) and ¶ 133 (See Faulkner Decl. Ex. P at UP0073224 ("… the application has become abandoned unintentionally on April 18, 2002, for failure to a file an Appeal Brief that was due on April 17, 2002, including *extensions of time that had been granted*"; "… this application became abandoned on April 18, 2002 the date the appeal brief was due, *including extensions of time actually granted*"; "the subject application became inadvertently abandoned on April 18, 2002, for failure to file the Appeal Brief that was due on April 17, 2002, *including extensions of time that had been granted*").

finding allowed the '752 patent to issue. FAC ¶¶ 134-137.

Genentech has also pled facts from which the Court may reasonably infer Bernstein (1) knew his misrepresentations that the PTO had granted an extension were false and (2) made these misrepresentations with the specific intent to deceive the PTO. *Exergen Corp.*, 575 F.3d at 1328-29. As to ***knowledge***, Genentech has alleged that [redacted] that "Mr. Bernstein also was aware of evidence—in addition to the file history he reviewed and PTO PAIR records—demonstrating that there was no need for the PTO to have granted a one-month extension of time in January of 2002;" and that "[a]t the time Mr. Bernstein filed his February 20, 2004 petition, he knew that 37 CFR 1.192(b) and MPEP 1207 governed filings made by an applicant after an appeal has been commenced. … He also knew at this time that the appeal process in the '800 application had, in fact, terminated before University of Pennsylvania filed any of its amendments with the PTO in 2002." FAC ¶¶ 124, 127, 129, 132. As to ***intent***, Genentech has alleged that despite being aware that the PTO had not granted the extension, Bernstein stated ***repeatedly***, and ***on two separate occasions***, that the PTO had in fact actually granted the petition. "While the making of a single material misrepresentation … may alone suffice to establish inequitable conduct, a pattern of such actions or omissions clearly argues against honest mistake and provides strong support for a ruling of inequitable conduct." *Mark Industries v. Mobile Scaffolding Management & Sales Inc.*, 1989 WL 418793 at *18 (C.D. Cal.1989) (*citing Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984)). Accordingly, Genentech has satisfied each of the pleading requirements under Rule 9(b) and *Exergen*.

Penn's opposition focuses solely on materiality and intent. First, Penn argues that even if Bernstein misrepresented that Penn had been granted an extension of time to file its appeal brief, those misrepresentations were not material, because "the PTO had the same materials available as Dr. Bernstein" and "PTO examiners are free to reach their own conclusions" and "should not thoughtlessly accept an applicant's interpretation." Opp. at 13-14.

The mere fact that the PTO has access to a document does not guarantee immunity from the consequences of an applicant's misconduct. "[L]apse on the part of the examiner does not

excuse the applicant. … There is no reprieve from the duty of square dealing and full disclosure that rests on the patent practitioner in dealings with the PTO. … [T]his duty is not done by one who knowingly takes advantage of an error by the PTO." *Kangaroos U.S.A., Inc. v. Caldor, Inc.*, 778 F.2d 1571, 1576 (Fed Cir. 1985) (holding that where plaintiff's agent made an improper claim of priority and "the PTO examiner could and should have checked," but did not, the duty of disclosure remained on the plaintiff). Thus, although it may be true that the PTO could have, and should have, checked to see whether Penn had, in fact, been granted an extension, Bernstein still had a duty not to affirmatively misrepresent this fact to the PTO. *See also Mechanical Plastic Corp. v. Rawlplug Co., Inc.*, 14 U.S.P.Q.2d 1058, 1061 (S.D.N.Y. 1989) (denying motion to strike inequitable conduct defense where patentee failed to advise the examiner of a prior inconsistent position in a PTO interference proceeding, even though the patent examiner was required to review the interference proceeding).

D. Genentech timely filed its motion to amend under the Court's scheduling order shortly after discovering the facts supporting its inequitable conduct allegations.

Penn's complaint that Genentech "inexcusably concealed" its inequitable conduct theory is curious in that, following a score of pages complaining that Genentech has not alleged sufficient details to meet Rule 9(b)'s requirements, Penn claims Genentech should have advanced those positions with *less* evidence. Surely an earlier filing would have drawn a cry from Penn that Genentech was prematurely speculating when it should take more discovery. And Penn studiously ignores that ***Genentech's motion is timely*** under this Court's scheduling order.

Penn fails to identify which additional piece of discovery Genentech unnecessarily pursued. Penn produced its supplemental interrogatory response identifying the incriminating high-dose experimental data as evidence of the inventors' conception and reduction to practice on September 24, 2010. Genentech promptly noticed Dr. Katsumata for deposition on October 14, 2010, but Katsumata refused to appear for deposition during the month of November. The deposition finally occurred on December 3, 2010. It was only during this deposition that Genentech discovered Katsumata had no explanation for the faulty evidence and could not point

to or recall any evidence for the inventors' statements in the '752 patent that half of the mice lived tumor-free for more than 90 weeks. Accordingly, and o*n the day of Katsumata's deposition*, Genentech issued Interrogatory Number 10, requesting that Penn "[f]ully explain the underlying data and basis of the statement (underlined below) found in Column 7, line 65 to Column 8, line 1 of the '752 patent, which states: The high dose treatment group of mice developed tumors after 45.6 weeks of age. However, 6 of 12 mice in this group (50%) remained free of tumors at more than 90 weeks of age." *See* Suppl. Faulkner Decl. Ex. 3 at 1. Penn responded on January 3, 2011, with unsubstantiated claims that "there may be additional experimental data." *See id.* Ex. 4 at 3. On January 14, 2011, Genentech performed an inspection of the original documents Penn produced, which included data sheets. Williams Decl. ¶ 4.

As for Mitchell Bernstein, Genentech noticed his deposition on November 30, 2010. See Kushan Decl. ¶ 2. Penn offered, and Genentech accepted, January 14, 2011 for his deposition. *Id.* ¶ 3. Less than three days before the deposition, Penn produced approximately 2207 pages of documents relevant to the deposition. *Id.* ¶ 5. Accordingly, the deposition was rescheduled and held on February 1, 2011. *Id.* ¶ 6. Genentech served its motion to amend on February 18, 2011. Penn's claim of concealment thus lacks any support.

Finally, Penn asserts Genentech's inequitable conduct allegations will beget an "extraordinary expansion" of the case and create "chaos" by requiring additional discovery. Opp. at 25. While that sounds ominous, it is an empty claim. The touchstone of undue delay is prejudice—here, Penn has identified none. Penn did not identify *any* discovery it purportedly needs and fails to explain why it cannot now, and could not in the intervening months since Genentech filed its motion to amend, speak with the inventors, scientists and attorneys, all of whom are ***Penn employees and collaborators,*** about the basis for Genentech's defense.

III. CONCLUSION

Accordingly, consistent with the federal policy favoring liberal amendment of the pleadings, Genentech respectfully moves the Court to permit Genentech to amend its complaint and answer.

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Respectfully submitted,

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